Supreme Court, U.S.
FILED

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In The

Supreme Court of the United States

October Term, 1996

Catherine W. Griffin,
Petitioner,

v.

Medtronic, Inc.,
Respondent,

On Petition for a Writ of Certiorari to
The United States Court of Appeals
For the Fourth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Do the Medical Device Amendments to the Food, Drug & Cosmetic Act preempt state law products liability claims, an issue on which the Fourth Circuit decision in this case directly conflicts with a relevant decision of the Supreme Court?

Catherine W. Griffin respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fourth Circuit in this case.

OPINIONS BELOW

The opinion of the Court of Appeals for the Fourth Circuit, App. at 1-9, is reported at 82 F.3d 79 (4th Cir. 1996). The opinion of the District Court for the District Court of Maryland, App. at 10-13, is reported at 840 F.Supp. 396 (D. Md. 1995).

JURISDICTION

The Petition for Rehearing was denied by the Court of Appeals on May 29, 1996. This Court has jurisdiction under 28 U.S.C. §1254(1).

CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED

U.S. Const., Article VI ..... App. 14

21 U.S.C. § 360k ..... App. 14-15

21 U.S.C. § 360h(d) ..... App. 15

21 C.F.R. § 808.1(d) ..... App. 15-16

STATEMENT OF THE CASE

Mrs. Griffin brought state products liability claims against Medtronic, Inc. seeking damages for the injuries caused by Medtronic cardiac

pacemakers. The district court granted summary judgment in favor of Medtronic, Inc., concluding that the Medical Device Amendments to the Food Drug and Cosmetic Act preempted all claims for damages under state law. The Court of Appeals for the Fourth Circuit largely affirmed, holding that the Amendments preempted all of Mrs. Griffin's product liability claims except for breach of express warranty.

A. Statement of Facts

Mrs. Griffin suffers from cardiac malfunction which required her to have a pacemaker implanted to artificially regulate, control and pace her heart. A cardiac pacemaker consists of a pulse generator and a lead or an electrode. In February of 1984, Mrs. Griffin had a Medtronic Spectrax model 8422 dual chamber generator and model 6972 polyurethane lead implanted. In March of 1986, this pacemaker failed and a Medtronic Spectrax model 8420 dual chamber generator and a Medtronic model 4012 polyurethane lead were implanted in her chest. In December of 1989, this pacemaker also failed and was explanted from Mrs. Griffin's chest. The failed leads remain implanted in Mrs. Griffin's chest. Both of the failed pacemakers were manufactured and sold by Medtronic.

The failed pacemakers are subject to the Medical Device Amendments of 1976 ("Amendments"). Under the Amendments, the FDA classifies all medical devices into three groups. 21 U.S.C. §360c(a). The FDA placed the pacemaker generators and leads implanted in Mrs. Griffin into Class III in 1980. 21 C.F.R. §870.3610. Both models were classified as substantially equivalent to devices in commercial distribution prior to May 28, 1976, the effective date of the Amendments. Medtronic therefore submitted a section 510(k) "premarket notification" on the grounds that its devices were "substantially equivalent to such devices". The 510(k) notification constitutes an exemption from the class III "premarket approval" regulatory process that would otherwise have applied to the devices. 21 U.S.C. §360c(f)(1).

B. Procedural History

This is a diversity action, originally brought by Catherine Griffin on December 4, 1992, a citizen of Maryland, in the Circuit Court for

Baltimore City, Maryland, which was removed to the United States District Court for the District of Maryland pursuant to 28 U.S.C. §1332. The district court granted summary judgment, holding that the Amendments preempted each of Mrs. Griffin's claims. App. at 10-13. The court of appeals affirmed except with respect to the claim for breach of express warranty based on warranties made apart from the labeling, packaging or promotion of the product. App. at 1-9.

REASONS FOR GRANTING THE PETITION

The preemptive scope the Amendments was defined by the Supreme Court on June 26, 1996. *Medtronic, Inc. v. Lohr,* 56 F.3d 1335 (11th Cir. 1995), Nos. 95-754 and 95-886 (June 26, 1996). The Fourth Circuit's decision this case directly conflicts with the Supreme Court's decision in *Lohr*.

I. The Fourth Circuit's Decision Irreconcilably Conflicts with Supreme Court Decisions

Griffin is in direct conflict with this Court's recent ruling in *Lohr* which creates an obvious, irreconcilable conflict: the Supreme Court held that the Amendments do not preempt products liability law, but here the Fourth Circuit found that almost all of Mrs. Griffin's claims are preempted. The courts differ both in their reading of the statute and, more fundamentally, in their approach to the doctrine of preemption.

On June 26, 1996, the Supreme Court announced its decision in *Medtronic, Inc. v. Lohr,* 56 F.3d 1335 (11th Cir. 1995), Nos. 95-754 and 95-886 (June 26, 1996). The Supreme Court held that the Medical Device Amendments do not preempt state tort claims, including negligent design claims and strict liability claims based upon defective design, manufacturing defect or failure to warn. *Id.*
This decision directly overrules the Fourth Circuit's opinion in *Griffin*.

The court in *Griffin* stated "[T]he preemption issues presented by this appeal are controlled by our recent decision in *Duvall*..." *Griffin v. Medtronic, Inc.*, 82 F.3d 79, 81 (4th Cir. 1996). On July 1, 1996, the Supreme Court granted certiorari and vacated the Fourth Circuit's

decision in *Duvall v. Bristol-Myers-Squibb, Co.*, 65 F.3d 392 (4th Cir. 1995), *vacated*, No. 95-1010 (July 1, 1996), and remanded the case for further proceedings. Like *Griffin*, *Duvall* involves preemption of state tort claims regarding a Class III medical device that was approved for marketing pursuant to a 510K "substantially equivalent" notification, not pursuant to a premarket approval process.

The Fourth Circuit decision in *Griffin*, which involves an important federal question, directly conflicts with the Supreme Court's decision in *Lohr*. Therefore, certiorari should be granted in this case. Furthermore, since the Fourth Circuit held that the preemption issues in *Griffin* were "controlled by our recent decision in *Duvall*", and last month the Supreme Court granted certiorari and vacated the Fourth Circuit's decision in *Duvall*, justice demands that certiorari be granted in this case.

CONCLUSION

For the above reasons, Mrs. Griffin respectfully requests that this Court grant her petition for a writ of certiorari.

Respectfully submitted,

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PUBLISHED
UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

CATHERINE W. GRIFFIN,	*	
	*	
Plaintiff-Appellant,	*	
v.	*	No. 94-1219
	*	
MEDTRONIC, INCORPORATED,	*	
	*	
Defendant-Appellee.	*	
	*	

* * * * * * * * * * * * * * *

Appeal from the United States District Court
for the District of Maryland, at Baltimore
Frederic N. Smalkin, District Judge.
(CA-93-60-S).

Argued: September 27, 1994.

Decided: April 30, 1996.

Before WIDENER and MOTZ, Circuit Judges, and MICHAEL, Senior United States District Judge for the Western District of Virginia, sitting by designation.

Affirmed by published opinion. Senior Judge MICHAEL wrote the opinion, in which Judge WIDENER and Judge MOTZ joined.

COUNSEL

ARGUED: Kristen Atkins Brinster, Seidenman, Sutherland & Lynn, P.A., Baltimore, Maryland, for Appellant. Harley Thomas Howell, Benjamin Rader Goertemiller, Howell, Gately, Whitney & Carter, Towson, Maryland, for Appellee. **ON BRIEF:** Jerome J. Seidenman, John R. Sutherland, Seidenman, Sutherland & Lynn, P.A., Baltimore, Maryland, for Appellant. John S. Bainbridge, Jr., Howell, Gately, Whitney & Carter, Towson, Maryland, for Appellee.

OPINION

MICHAEL, Senior District Judge:

Catherine Griffin appeals the decision of the district court granting summary judgment to Medtronic, Inc. ("Medtronic") on the grounds that Griffin's claims are preempted by 21 U.S.C.A. § 360k (West Supp.1995), enacted as part of the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug, and Cosmetic Act. On the recent authority of *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir.1995), we affirm in part, reverse in part and remand.

I.

In 1984, a pacemaker, manufactured and sold by Medtronic, was implanted in Griffin's chest to help regulate and control her heart rate. The pacemaker consisted of a dual chamber generator and polyurethane leads. In 1986, the pacemaker failed and was removed. However, portions of the leads remained in Griffin's chest. Griffin's physicians inserted a new Medtronic pacemaker which ultimately failed in 1989. Doctors removed most of the second pacemaker, but once again, portions of the leads remained in Griffin's chest. Griffin then received yet another Medtronic pacemaker which has not functioned properly to date, allegedly because of the remnants of the leads left in Griffin's chest.

In 1992, Griffin brought the current suit against Medtronic in

Maryland state court. Her complaint states five counts: (1) negligent design and manufacture; (2) breach of express warranty; (3) breach of an implied warranty of fitness for a particular purpose; (4) strict liability for defective manufacture; and (5) intentional misrepresentation of the defective condition of the pacemakers. Medtronic removed the case to federal court on the basis of diversity of citizenship.

The district court, relying on the authority of *Stamps v. Collagen Corp.*, 983 F.2d 1416 (5th Cir.1993), and *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.1993), ruled that Griffin's claims were preempted by § 360k of the MDA[1] and, accordingly, granted Medtronic's motion for summary judgment. No material facts are in dispute. The appeal presents questions of law subject to de novo review. *Higgins v. E.I. DuPont de Nemours & Co.*, 863 F.2d 1162, 1166-1167 (4th Cir.1988).

II.

A.

The preemption issues presented by this appeal are controlled by our recent decision in *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir.1995). The plaintiff in *Duvall* brought several state-law claims against the manufacturer of a penile prosthesis after undergoing surgery to implant the prosthesis.[2] In ruling that the majority of plaintiff's claims

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1 Subject to a possible exemption not claimed here, section 360K provides that:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C.A. § 360k.

2 Under the framework of the MDA, penile inflatable implants are classified as "Class III" medical devices, and as such, are subject to the most rigorous regulation. *Duvall*, 65 F.3d at 396, 21 C.F.R. § 876.3350 (1995). A manufacturer must generally receive approval from the Food

were preempted by § 360k, we held that "state-law claims are preempted by § 360k to the extent that, if successful, such claims would impose requirements under state law different from or in addition to requirements applicable to a device under the MDA." *Id.* at 398. With this language as a baseline, we concluded that plaintiff's breach of implied warranty, strict liability, and negligence claims were necessarily preempted by § 360k. However, we held with respect to plaintiff's breach of express warranty claim that "although § 360k preempts express warranty claims to the extent that they are based on FDA-mandated labeling, packaging, and advertising, it does not preempt an express warranty claim that is based on a manufacturer's voluntarily-made representations regarding its product." *Id.* at 400-401. We therefore reversed and remanded, for further consideration in light of that holding, the district court's grant of summary judgment for Medtronic on the express warranty claim.

B.

[1] Given the authority of *Duvall*, we deal only briefly with Griffin's arguments.[3] Griffin's breach of implied warranty, strict liability, and negligence claims are preempted by § 360k because were Griffin to prevail on those claims, Medtronic would be burdened with requirements different from or in addition to those applicable to pacemakers under the MDA. As did the plaintiff in *Duvall*, Griffin here argues that these state-law claims, if successful, would not impose any different or additional requirements on Medtronic because the MDA does not impose specific requirements on pacemakers in the first instance.

---

and Drug Administration ("FDA") before marketing a Class III device. However, the prosthesis was brought to market via the "substantially equivalent" mechanism outlined at 21 C.F.R. § 807.100(a) (1995). *Id.* Under this administrative regime, a Class III device for which the FDA does not yet require the usual premarket approval may be marketed if the manufacturer shows that the device is "substantially equivalent" to a device marketed before the effective date of the MDA. *Id.* The pacemakers issue in this case are also Class III medical devices, 21 C.F.R. § 870.3610 (1995), brought to market under the authority of the "substantially equivalent" process.

3 In fairness to Griffin, we note that argument was heard on Griffin's appeal before *Duvall* was decided.

However, we held in *Duvall* that the premarket notification procedure under the MDA, codified at 21 C.F.R. § 807.87 (1995) and known as 510(k) Notification, constitutes a requirement applicable to devices under the MDA because the notification procedure requires a manufacturer to submit to the FDA, among other things, certain descriptive particulars, such as proposed labels and advertisements. *Id.* at 400 ("510(k) Notification is a requirement applicable to the device under the MDA"). Thus, successful state-law claims would indeed impose a requirement in addition to a requirement already imposed on pacemakers under the MDA. Accordingly, Griffin's breach of implied warranty, strict liability, and negligence claims are preempted by § 360k.

[2] With respect to Griffin's express warranty claim, we must return the case to the district court to determine whether the claim is based on promises voluntarily made by Medtronic--and therefore, not preempted by § 360k--or whether it is based on FDA-mandated labeling, packaging, and advertising of Medtronic's pacemakers--and therefore preempted by § 360k.

III.

[3] Griffin's complaint contains one count of intentional misrepresentation. This claim alleges that Medtronic did not disclose the fact that the pacemakers were defective and unsafe for human use. Although we were not presented with an intentional misrepresentation claim in *Duvall*, we believe the rationale of *Duvall* mandates that we affirm the decision of the district court granting summary judgment for Medtronic on that claim.

[4] We reach this conclusion because the record in this case reveals no statements or other communications made to Griffin or to her physician that are any different from those made to the FDA. Thus, the premise of Griffin's intentional misrepresentation claim is that Medtronic had a duty to disclose information to Griffin and to her physician different from that which Medtronic provided to the FDA.[4] If successful,

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4 Of course, Griffin's claim might also be premised on the notion that Medtronic did not adequately comply with FDA disclosure requirements. However, the FDA alone is empowered to enforce its regulations. A private right of action seeking enforcement of FDA regulations has not been

this claim would result in the imposition of a requirement above and beyond those imposed by the MDA. Under *Duvall*, such state-law claims are preempted. Accordingly, we conclude that Griffin's intentional misrepresentation claim is preempted.

IV.

Under the authority of *Duvall*, we affirm the decision of the district court granting summary judgment for Medtronic on Griffin's negligence, breach of implied warranty, strict liability, and intentional misrepresentation claims. However, we reverse in part and remand the case with respect to Griffin's breach of express warranty claim for further proceedings not inconsistent with this opinion.

AFFIRMED IN PART; REVERSED AND REMANDED IN PART.

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recognized. *See, e.g., Rodriguez v. SK & F Co.*, 833 F.2d 8, 9 (1st Cir.1987), and cases cited therein.

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

FILED
June 6, 1996

No. 94-1219
CA-93-60-S

Griffin v. Medtronic , Inc.

MANDATE

The judgment of this Court dated 4/30/96 takes effect today.

BERT M. MONTAGUE
CLERK

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

FILED
May 29, 1996

No. 94-1219
CA-93-60-S

CATHERINE W. GRIFFIN
Plaintiff - Appellant

v.

MEDTRONIC, INCORPORATED
Defendant - Appellee

On Petition for Rehearing with Suggestion for Rehearing In Banc

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The appellant's petition for rehearing and suggestion for rehearing in banc were submitted to this court. As no member of this Court or the panel requested a poll on the suggestion for rehearing in banc, and

As the panel considered the petition for rehearing and is of the opinion that it should be denied.

IT IS ORDERED that the petition for rehearing and suggestion for rehearing in banc are denied.

For the Court,

/s/ Bert M. Montague

CLERK

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

CATHERINE W. GRIFFIN	*	
PLAINTIFF	*	Civil No. S 93-60
V.	*	
MEDTRONIC, INC.	*	
DEFENDANT.	*	

* * * * * * * * * * * * *

MEMORANDUM OPINION

This is a product liability case, asserting numerous state-law based tort claims for injuries allegedly caused by defendant's implantable pulse generators and cardiac leads, commonly known together as "pacemakers." Both pacemakers allegedly failed after their sequential implantation in plaintiff, certain parts of the leads allegedly proved unremovable, and, it is also alleged, the consequences of these failed implantations have prevented plaintiff from properly employing her latest pacemaker to its fullest designed extent. The defendant now moves for summary judgment on the ground that plaintiff's claims are pre-empted by the so-called Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §360K. The plaintiff opposes summary judgment. No oral hearing is needed. Local Rule 105.6, D.Md.

This summary judgment motion presents only an issue of law, there being no facts material to the pre-emption question in dispute. Thus, defendant may prevail only in the event it demonstrates a clear entitlement to judgment in its favor as a matter of law. Fed. R. Civ. P. 56(c).

There is no question that the alleged injuries in this case are attributed to Class III Medical Devices, regulated under the MDA. Upon

consideration, this Court has decided to follow the decisions of the First and Fifth Circuits, both of which have very recently addressed the question squarely presented in this case, viz., whether the MDA pre-empts state-law based causes of action in product liability cases involving regulated devices. Both circuits have said that such claims are pre-empted. See Stamps v. Collagen Corp., 984 F.2d 1416 (5th Cir. 1993); King v. Collagen Corp., 983 F.2d 1130 (1st Cir. 1993). It would serve no useful purpose for this Court to re-hash the thorough analyses of those Circuits here.

Plaintiff's attempts to distinguish these cases are unconvincing. Both cases took full account of the Supreme Court's latest pronouncements on federal pre-emption. Both squarely dealt with the cardinal issue in this case. Neither is inconsistent with prior case law in this Circuit or District, viz., Abbott v. The American Cyanamid Co., 844 F.2d 108 (4th Cir. 1988), and Callen v. G.D. Searle & Co., 844 F.2d 662 (D.Md. 1989), in that those cases did not involve devices, but, rather, drugs. Both of those cases were decided before the Supreme Court's decision in the seminal case of Cipollone v. Liggett Group, Inc., _____ U.S. _____, 112 S.Ct. 2608 (1992), which especially calls into question the continued reliability of the discussion in Callan concerning §360K.

Finally, plaintiff argues that, even if pre-emption were to be found by the Court, it should not extend to her fraud claim. To the extent that her claim mirrors the one discussed in King, 983 F.2d at 1139-40, this Court rejects it, for the same reasons as did the King court. To the extent that plaintiff makes the claim that defendant's fraud on the medical community, including prescribing doctors, entitles her to proceed, and ultimately to relief, she is barred by Maryland's requirement that fraudulent misrepresentations must be made to the plaintiff who is claiming injury from her reliance on those representations, not to third parties. Such was the flat holding of Parlette v. Parlette, 88 Md. App. 628, 635 (1991) (opinion by Diana Motz, J.), which appears to be the only Maryland authority on point. Even in jurisdictions following a broader rule as to the class of potential fraud plaintiffs, see, e.g., Institute for Professional Dev. v. Regis College, 536 F.Supp. 632, 634 (D. Colo. 1982), the rule is that the plaintiff must be within the targeted class, i.e., those "intended to be influenced." Here, there is no allegation that defendant's fraud was targeted at consumers, as

was the case in Cipollone, but, rather at the FDA and the medical community. In any case, patients were not themselves targeted, as they obviously do not choose a particular prescription medical device such as a pacemaker, based on manufacturers' representatives or otherwise. Thus, under Maryland law as recited in Parlette, there is simply no fraud claim that survives pre-emption.

For the stated reason, an order will be entered granting summary judgment to the defendant.

Dated: January 11, 1994

/s/
Frederic N. Smalkin
U.S. District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

CATHERINE W. GRIFFIN	*	
	*	
Plaintiff	*	Civil No. S 93-60
	*	
V.	*	
	*	
MEDTRONIC, INC.	*	
	*	
Defendant	*	
	*	

* * * * * * * * * * * * *

JUDGMENT ORDER

For the reasons stated by the Court in a Memorandum Opinion entered herein this date, it is, by the Court, this 11th day of January, 1994, ORDERED and ADJUDGED:

1. That the defendant's motion for summary judgment BE, and it hereby IS, GRANTED;

2. That judgment BE, and it hereby IS, ENTERED for the defendant, against the plaintiff, with costs; and

3. That the Clerk mail copies hereof and of the foregoing Memorandum Opinion to counsel.

/s/
Frederic N. Smalkin
U.S. District Judge

CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED

Article VI of the U.S. Constitution provides in pertinent part:

> This Constitution, and the Laws of the United States...shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

21 U.S.C. § 360k provides:

(a) General rule

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement -
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

> Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if -
>
> > (1) the requirement is more stringent than a requirement under this chapter which would be

applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement -

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 U.S.C. § 360h(d) provides:

Effect on other liability. Compliance with an order under this section shall not relieve any person of liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

21 C.F.R. § 808.1(d) provides in pertinent part:

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices

(e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

No. 96-603

Supreme Court, U.S.
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DEC 30 1996
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In the Supreme Court of the United States

OCTOBER TERM, 1996

CATHERINE W. GRIFFIN, PETITIONER

v.

MEDTRONIC, INC., RESPONDENT

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

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42 pp

QUESTIONS PRESENTED

1. Whether this Court should grant plenary review and reconsider its fractured decision last Term in *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240 (1996), concerning the preemptive scope of the Medical Device Amendments to the federal Food, Drug, & Cosmetic Act, 21 U.S.C. § 360k(a), in view of the widespread confusion that decision has already engendered in the lower courts in medical device cases, the doctrinal uncertainty it has interjected more generally into preemption law, and the serious ambiguities and errors in the Court's analysis.

2. Whether this Court should grant review to resolve the inconsistencies in its past decisions concerning whether an administrative agency's interpretation of an express preemption clause is entitled to deference under *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

RULE 29.6 STATEMENT

Respondent Medtronic, Inc. (Medtronic) has no parent company. Medtronic's wholly-owned subsidiary, Synectics Medical A.B. (Synectics), has the following subsidiaries that are not wholly owned by Synectics:

Synectics GmbH
CTD Synectics Ltd.
Synectics IR SA,
Synectics Medical Co., Ltd.
Zinetics Medical, Inc.

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BRIEF FOR THE RESPONDENT

Respondent Medtronic, Inc., agrees that the petition for a writ of certiorari should be granted to review the judgment of the United States Court of Appeals for the Fourth Circuit in this case. For the reasons set forth below, Medtronic urges the Court to grant plenary review and reconsider its fractured decision last Term in *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240 (1996), which contains a number of serious ambiguities and errors and has spawned confusion and conflicting results in the lower courts.

STATEMENT

A. The Proceedings Below

This product liability action arises out of petitioner Catherine Griffin's successive use of two implantable pacemakers manufactured by respondent Medtronic. Claiming that the pacemakers (each of which consists of a pulse generator and polyurethane "leads" that deliver the pulse to the heart) failed to function properly, and that certain parts of the leads proved unremovable, Griffin filed suit in Maryland state court alleging (1) negligent design and manufacture, (2) breach of express warranty, (3) breach of implied warranty of fitness for a particular purpose, (4) strict liability for defective manufacture, and (5) intentional misrepresentation of the defective condition of the pacemakers. Medtronic removed the case to federal court and moved for summary judgment on the ground that all of Griffin's claims are expressly preempted by the Medical Device Amendments ("MDA") to the federal Food, Drug, & Cosmetic Act, 21 U.S.C. § 360k(a). The district court granted the motion. Pet. App. 9-11.

The district court observed that the pacemakers at issue are "Class III Medical Devices, regulated under the MDA." Pet. App. 9. Class III devices are "subject to the most rigorous regulation" under the MDA. *Id.* at 3 n.2. As petitioner correctly notes, both of the relevant Medtronic pacemakers are so-called "510(k) devices" that came to market on the basis of their "substantial equivalence" to devices that were on the market before 1976, when the MDA was enacted. Pet. 2; Pet. App. 4 n.2, 5.

In concluding that all of petitioner's claims are preempted, the district court relied on decisions from the First and Fifth Circuits. See Pet. App. 10 (citing *King* v. *Collagen*, 983 F.2d 1130 (1st Cir.), cert. denied, 510 U.S. 824 (1993), and *Stamps* v. *Collagen*,

984 F.2d 1416 (5th Cir.), cert. denied, 510 U.S. 824 (1993)). It also specifically rejected petitioner's argument that her fraud claim is not preempted. The district court explained that, to the extent petitioner was alleging a fraud on the federal Food and Drug Administration ("FDA"), the expert federal agency that administers and enforces the MDA, her claim is preempted for the reasons set forth in *King*. Pet. App. 10. And, to the extent petitioner was claiming a fraud on the medical community, that theory is not cognizable under Maryland law. *Id.* at 10-11.

The Fourth Circuit affirmed in part and reversed in part. Pet. App. 1-6. The court of appeals explained that its preemption analysis was controlled by *Duvall* v. *Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995), which held that state-law claims of breach of implied warranty, strict liability, and negligence relating to a 510(k) device were all "necessarily preempted by § 360k." Pet. App. 4. Section 360k(a) provides:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use *any requirement* — (1) which is different from, or in addition to, *any requirement* applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added).

Under *Duvall*, the court of appeals explained, Griffin's "breach of implied warranty, strict liability, and negligence claims are preempted by § 360k because were Griffin to prevail on those claims, Medtronic would be burdened with requirements different from or in addition to those applicable to pacemakers under the MDA." Pet. App. 4. Griffin's claim of intentional misrepresentation, the court stated, was also preempted under "the rationale of *Duvall*." *Id.* at 5. With regard to petitioner's express warranty claim, the court, again relying on *Duvall*, concluded that it "must return the case to the district court to determine whether the claim is based on promises voluntarily made by Medtronic — and therefore, not preempted by § 360k — or whether it is based on FDA-

mandated labeling, packaging, and advertising of Medtronic's pacemakers — and therefore preempted by § 360k." *Ibid.*

B. This Court's Decision In *Medtronic* v. *Lohr*

After the Fourth Circuit denied rehearing, this Court decided *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240 (1996). The decision consists of three separate opinions, which combine in different ways to address the issues in the case: (1) Justice Stevens's opinion, which was joined by Justices Kennedy, Souter, and Ginsburg; (2) Justice O'Connor's partial concurrence and dissent, which was joined by Chief Justice Rehnquist and by Justices Scalia and Thomas; and (3) Justice Breyer's separate opinion concurring in part and concurring in the judgment, which joins Justice Stevens's opinion in part but also partially agrees with the reasoning of Justice O'Connor's opinion. The Court unanimously concluded that the Lohrs' *design defect* claims based on state common law (and other claims embodying state requirements that were identical to applicable federal requirements) were not preempted by the MDA, but a 5-4 majority held that the manufacturing and warning claims were not preempted.[1]

The preemption issues presented in this case are in many respects similar to those decided in *Lohr*. The pacemakers involved here, like the device at issue in *Lohr*, are 510(k) devices brought to market on the basis of a determination by the FDA of their "substantial equivalence" to pre-MDA devices. Here too, as in *Lohr*, the express preemption analysis turns on the meaning of 21 U.S.C. § 360k(a). And petitioner Griffin, like Ms. Lohr, advances claims of negligence and strict liability in the design and manufacturing of the device.[2] Because of these substantial similarities, review by this Court is appropriate. For the reasons

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[1] Following its *Lohr* decision, this Court granted review in *Duvall*, vacated the decision below, and remanded to the Fourth Circuit. 116 S. Ct. 2575 (1996). On remand, the Fourth Circuit concluded that Duvall's claims are not preempted under the MDA. See *Duvall* v. *Bristol-Myers-Squibb Co.*, 1996 U.S. App. LEXIS 33037 (Dec. 18, 1996).

[2] Unlike Ms. Lohr, however, petitioner Griffin advances an *express warranty* claim and alleges a "fraud-on-the-FDA" theory of liability.

described below, however, we urge the Court to grant plenary review rather than to vacate and remand to the Fourth Circuit for further proceedings in light of *Lohr*.

ARGUMENT

This Court's fractured *Lohr* decision contains a number of significant ambiguities and threatens to interject great uncertainty into the law governing preemption under the Medical Device Amendments, 21 U.S.C. § 360k(a). As we explain below, the lower courts are already in disarray in their efforts to understand and apply the majority's analysis. Even beyond the medical device area, the *Lohr* decision sows confusion about principles of preemption, which is of vital importance to a broad range of businesses in the national economy. Plenary revisitation of the issues raised in *Lohr* and in this case would better serve this Court's function of guiding the lower courts than would an unelaborated remand.

Moreover, and with all due respect, the opinions of Justice Stevens and Breyer contain a number of serious analytical flaws and rely on premises about the statutory scheme and the FDA's administrative practice that are demonstrably incorrect. In addition, the *Lohr* majority's heavy reliance on an FDA interpretation of the MDA's express preemption clause — without first deciding the threshold issue of the appropriateness in this context of deference under *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) — is at odds with a previous decision of this Court and threatens to create further confusion in the law concerning *Chevron*. To decide this important question of administrative law, and to reconsider a recent decision that four Members of this Court described as "bewildering and seemingly without guiding principle" (116 S. Ct. at 2262 (opinion of O'Connor, J.)), this Court should grant the petition and revisit its decision in *Lohr*.

I. The *Lohr* Opinions Contain Significant Ambiguities And Have Already Produced Confusion And Divergent Outcomes In The Lower Courts

The Court's *Lohr* decision contains a number of serious ambiguities, which have not gone unnoticed by courts and commentators. In *Lohr* itself, four Members of this Court described the plurality's analysis as "bewildering and seemingly without guiding principle." 116 S. Ct. at 2262 (opinion of O'Connor, J.). Writ-

ing for the court in a case involving express preemption under the Flammable Fabrics Act, 15 U.S.C. § 1203(a), Judge Boudin recently observed that in preemption cases "the Supreme Court's inclination is balanced almost on a knife edge, as the divisions in *Lohr* amply confirm." *Wilson* v. *Bradlees of New England, Inc.*, 96 F.3d 552, 556 (1st Cir. 1996). Judge Boudin added:

> Resolution of this appeal was delayed in the hope that the then-anticipated decision of the Supreme Court in *Lohr* would provide more guidance than ultimately proved to be the case. Not only is *Lohr* not conclusive on our own issue, but the divisions there make even more general forecasts shaky. Absent guidance, we have done as best we can with these difficult problems of preemption in a changing legal climate.

Id. at 559; see also *Grenier* v. *Vermont Log Buildings, Inc.*, 96 F.3d 559, 564 (1st Cir. 1996) ("As *Lohr* illustrates, the signals from the Supreme Court are blurred by disagreements within the Court."); *Ketchum* v. *Hyundai Motor Corp.*, 49 Cal. App. 4th 1672, 1678, 57 Cal. Rptr. 595 (2d Dist. Ct. App. 1996) (Court was "widely divided" in *Lohr*).

Commentators have also noted the decision's ambiguities. See, *e.g.*, Amor Esteban and Shanna Davis, *'Medtronic': One Step Forward, Two Steps Back*, 24 PROD. SAFETY & LIAB. RPTR. 1054 (Nov. 8, 1996) (describing *Lohr* as "splintered decision of questionable scope" that "leaves the pre-emption doctrine largely unsettled"); *id.* at 1056 (of "questionable precedential value"); *id.* at 1058 (decision's "meaning, scope and persuasiveness" will be "largely for the lower courts to determine given the decision's lack of direction and the [J]ustices' divergent views"); Lars Noah, *The Pre-emption Morass*, TEX. LAWYER 26 (Aug. 12, 1996) (decision "only confused matters further"); *ibid.* ("Given * * * the court's failure to achieve some broader agreement on the precise contours of whatever pre-emption defense might exist in a particular case, lower courts will have to continue grappling with these difficult questions, and litigants can expect additional uncertainty."); *The Medtronic Tonic: A Preemption Prognosis*, PROD. LIAB. LAW & STRATEGY 1 (July 1996) (stating that the "[d]ebate will likely be prolific" over *Lohr*'s meaning because the Court's "message is not so clear"); R. Lawrence Purdy and Michael C. McCarthy, *Medtronic, Inc. v. Lohr: A Work In Progress*, MEALEY'S LITIGATION

REPORTS: BREAST IMPLANTS 21 (July 30, 1996) (*Lohr* "leaves the parties and their counsel in device litigation in an uncertain state" and relegates to the lower courts "the difficult task of applying the fractured holding"); Robert N. Weiner, *Making No Sense of Preemption Law: Medtronic, Inc. v. Lohr*, 25 PROD. SAFETY & LIAB. RPTR. __ (forthcoming) (draft at 1) (decision "raises as many questions as it answers regarding the law of preemption"; court's "splintering * * * amplifies the confusion"); *id.* at 25 (*Lohr* opinions "ensure[ ] that litigation on this subject will continue apace").[3]

As we will now discuss, several of those ambiguities could be clarified by a grant of plenary review in this case, with overwhelming benefit for lower courts and litigants alike.

A. As Justice O'Connor pointed out for four Members of this Court (116 S. Ct. at 2263), Justice Stevens's opinion appears to contain several internal contradictions. For example, it devotes significant space to explaining why the MDA's express preemption of state "requirements" does not, as a general matter, cover common law duties (116 S. Ct. at 2251-53); but it later acknowledges that a common law action might qualify as a state "requirement" (adding cryptically, however, that such cases would be "rare indeed") (*id.* at 2259).[4] Similarly, Justice Stevens's opinion says that it gives "substantial weight" to the FDA's interpretation of the MDA's preemption provision and, on that basis, concludes that the MDA triggers preemption only when there are a "specific" state requirement and a "specific" federal requirement applicable to the particular device (*id.* at 2256-58); yet it also indicates a willingness

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[3] See also Eva Rodriguez, *Confusion from the High Court*, CONN. LAW TRIB. 9 (July 15, 1996); *Uncertainty Remains Over Pre-emption After Court Ruling on Medical Devices*, BNA HEALTH CARE DAILY (July 2, 1996); Editorial, *The High Court's Flip Flops*, ROCKY MOUNTAIN NEWS 64A (July 4, 1996) (stating that *Lohr* "resembles less a ruling that the multiple choices of an opinion poll").

[4] The Missouri Supreme Court has interpreted Justice Stevens's opinion as saying that preemption occurs under the MDA only if there is a positive enactment of state law. *Connelly* v. *Iolab Corp.*, 927 S.W.2d 848, 852-53 (1996).

to disregard the agency's interpretation in other cases, stating that the Court "do[es] not believe that th[e] statutory and regulatory language necessarily precludes 'general' federal requirements from ever pre-empting state requirements, or 'general' state requirements from ever being pre-empted" (*id.* at 2257).[5]

B. Additional significant ambiguities arise as a consequence of Justice Breyer's opinion and vote. Justice Breyer joined Part III of Justice Stevens's opinion, which endorses a "presumption" against preemption in this context. Part III also indicates that, in express preemption cases, the Court's task is not simply to effectuate the ordinary meaning of Congress's language but rather to implement the Court's "reasoned understanding" of "the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." 116 S. Ct. at 2251. At the same time, Justice Breyer disagreed with the plurality's efforts to distinguish *Cipollone* v. *Liggett Group*, 505 U.S. 504 (1993), and agreed with Justice O'Connor that the

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[5] Part IV of Justice Stevens's opinion (which Justice Breyer did not join) is devoted to addressing an argument (attributed by the plurality to Medtronic) that "[i]n essence * * * the plain language of the statute preempts *any and all* common-law claims brought by an injured plaintiff against a manufacturer of medical devices." 116 S. Ct. at 2251 (emphasis added); *id.* at 2253 (referring to Medtronic's "extreme position"). But Medtronic did not take that position in *Lohr*. Medtronic argued that the word "requirement" in the MDA necessarily includes common law duties and that, accordingly, such duties are preempted whenever there is a "federal requirement" *on the same subject matter in place* (but not when no such federal requirement exists). See Nos. 95-754, 95-886 Pet. Reply Br. 3. In addition, Medtronic acknowledged that, to be subject to preemption, a state requirement must "relate[ ] to the safety or effectiveness of the device or any other matter included in a [federal] requirement" (21 U.S.C. § 360k(a)) — a formulation that necessarily would exclude certain kinds of common law claims. Nos. 95-754, 95-886 Pet. Reply Br. 3-4; Nos. 95-754, 95-886 Cross-Resp. Br. 18 n.18. Medtronic also conceded that the FDA could exempt state requirements from preemption by virtue of its authority under § 360k(b). Nos. 95-754, 95-886 Cross-Resp. Br. 16. And Medtronic took no position on whether express warranty or other claims not involved in the case might survive preemption under the reasoning of *Cipollone* v. *Liggett Group*, 505 U.S. 504 (1993).

"statute's language, read literally" — in particular its reference to state "requirements" — easily encompasses common law duties. 116 S. Ct. at 2259. Justice Breyer's willingness to read the preemption clause according to its ordinary meaning is consistent with the methodological approach of Justice O'Connor's opinion but at odds with the use of any "presumption" against preemption as an interpretive guide to construing an express preemption clause. This internal tension within Justice Breyer's opinion may well lead to confusion even outside the MDA context: Justice Breyer, after all, cast the deciding vote for a Court that appears to be otherwise evenly divided over the proper method of interpreting express preemption clauses.[6]

A second critical ambiguity stems from the fact that Justice Breyer joined all of Part V of Justice Stevens's opinion. In his separate opinion, Justice Breyer, relying on the FDA's interpretation of Section 360k(a), concluded that the federal requirements involved in *Lohr* were not sufficiently "specific" to trigger preemption. His focus was almost entirely on the *federal* rather than the *state* requirements involved in the case.[7] Moreover, when discussing which *state* requirements are preempted by the statute, Justice Breyer "basically agree[d]" with Justice O'Connor's analysis, concluding that "ordinarily, insofar as the MDA

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[6] In *Wilson* v. *Bradlees of New England*, 96 F.3d 552 (1st Cir. 1996), Judge Boudin, writing for the court, pointedly refused to rely on any presumption against preemption because, in light of the divisions in *Lohr*, "[i]t is not entirely clear how much force this proposition retains in the construction of express preemption clauses." *Id.* at 557. But see, *e.g.*, *Ketchum* v. *Hyundai Motor Corp.*, 49 Cal. App. 4th 1672, 1677-78, 1680, 57 Cal. Rptr. 595 (2d Dist. Ct. App. 1996) (relying on *Lohr*'s discussion of presumption in holding plaintiffs' claims not preempted by National Traffic and Motor Vehicle Safety Act).

[7] See 116 S. Ct. at 2261 ("Insofar as there are any applicable *FDA requirements here*, those requirements, even if numerous, *are not 'specific'* in any relevant sense.") (emphasis added); *ibid.* (concluding on that basis that the FDA "does not intend these requirements to pre-empt the state requirements at issue here"); *ibid.* ("At least in present circumstances, no law forces the FDA to make *its requirements* pre-emptive if it does not think it appropriate.") (emphasis added).

pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that *takes the form of a standard of care or behavior imposed by a state-law tort action.*" 116 S. Ct. at 2259, 2260 (emphasis added).

Notwithstanding his focus on the federal requirements applicable to Medtronic's pacemaker and his acknowledgment that the MDA may expressly preempt a "standard of care" embodied in state common law, Justice Breyer inexplicably joined Part V of Justice Stevens's opinion in its entirety. Part V contains a concluding paragraph (discussing the Lohrs' manufacturing and labeling claims) that suggests that the *state* requirements embodied in the Lohrs' claims are not preempted because they impose common law standards of care that are framed in general terms and are therefore not sufficiently "specific." 116 S. Ct. at 2258 (stating that the Lohrs' negligent manufacturing claim is not preempted because it is based on a "general duty * * * to use due care"). Whether Justice Breyer agreed with this analysis, or meant instead to rest his vote entirely on the generality of the *federal* requirements, is unclear. Equally unclear is how the statements in Part V of Justice Stevens's opinion concerning the generality of the common law standards of care can be reconciled with Justice Breyer's statements in his separate opinion. Because Justice Breyer cast the deciding vote in making Part V the opinion of the Court, these aspects of *Lohr* are likely to spawn confusion and additional litigation in the lower courts.

C. Another ambiguity lies in the degree of weight that should be accorded to the FDA's interpretation of the MDA's preemption provision. The opinions of Justices Stevens and Breyer both rely to a significant extent on an FDA regulation (21 C.F.R. § 808.1) that interprets the MDA's express preemption provision. See, *e.g.*, 116 S. Ct. at 2255 (Stevens, J.) ("our interpretation of the pre-emption statute is *substantially informed* by those regulations") (emphasis added); *id.* at 2256 (stating that there is a "sound basis" for giving "substantial weight to the agency's view of the statute"); *id.* at 2260 (opinion of Breyer, J.) (stating that it "makes sense" to infer that FDA "possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect"). Although both opinions cite *Chevron U.S.A.*

Inc. v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), neither explicitly says that *Chevron* deference is being accorded to the FDA's interpretation. Indeed, as noted above, a portion of Justice Stevens's opinion in which Justice Breyer joined indicates that the Court would be free, in some circumstances, to disregard the FDA's interpretation. See 116 S. Ct. at 2257 (stating that "we do not believe" that the FDA's "regulatory language necessarily precludes 'general' federal requirements from ever pre-empting state requirements, or 'general' state requirements from ever being pre-empted"). As Justice O'Connor correctly pointed out, the majority did "not admit to deferring to these regulations" under *Chevron*. 116 S. Ct. at 2263. Justice O'Connor's opinion also states that "[i]t is not certain that an agency regulation determining the pre-emptive effect of *any* federal statute is entitled to deference" but concludes that, even if it were, deference to the FDA's interpretation would be unwarranted because the statutory language is unambiguous. *Ibid.* (emphasis added).

The lower courts thus face the difficult quandary of determining what amount of weight to accord to the FDA's regulation when four Justices said it should receive no deference and five Justices, in two separate opinions, gave it some weight without explicitly deferring. This issue — unsettled by this Court in *Lohr* — deserves further attention, not only to clarify the degree of deference due the FDA but also to clarify the law governing deference to agency interpretations of express preemption clauses in general. See pages 24-28 & note 18, *infra*.

D. Yet another significant ambiguity is the extent to which the majority rested its conclusion that the Lohrs' manufacturing and labeling claims were not preempted on the *absence of a conflict* between the applicable state and federal requirements, as opposed to the *non-specificity* of those requirements.

Writing for a plurality, Justice Stevens took note of "the critical importance of device-specificity in our (and the FDA's) construction of § 360k." 116 S. Ct. at 2259. Writing for a majority, however, Justice Stevens stated that it is "impossible to ignore" Congress's "overarching concern that preemption occur only where a particular state requirement *threatens to interfere* with a specific federal interest." *Id.* at 2257 (emphasis added); see

also *id.* at 2252 (observing that, "when Congress enacted § 360k, it was primarily concerned with the problem of specific, *conflicting* State statutes and regulations") (emphasis added). And, in explaining why the Lohrs' manufacturing and labeling claims were not preempted, the majority made reference not only to the absence of specificity in the applicable requirements but also to the absence of a conflict between state and federal requirements.[8] These references to the idea of conflicting state and federal requirements could be interpreted in at least two ways: (1) as descriptions of Congress's preemptive intent underlying the MDA; or (2) as explanations of why the MDA's preemption clause targets only those requirements that are "specific" in nature.

Unfortunately, Justice Breyer's separate opinion does not clarify this point. Justice Breyer cited as pertinent to his analysis both the existence of an FDA interpretation limiting the preemption provision to "specific" requirements and his view that "ordinary principles of 'field' and 'conflict' preemption point in the same direction." 116 S. Ct. at 2261.

The lower courts are already divided over whether the *Lohr* holding hinges on the absence-of-a-*conflict* rationale or on the absence of federal and state requirements of sufficient *specificity*. The Missouri Supreme Court has interpreted Justice Breyer's vote as resting on the absence-of-a-conflict rationale and, accordingly, treats that rationale as the holding of the *Lohr* majority. See *Connelly* v. *Iolab Corp.*, 927 S.W.2d 848, 852-54 (1996). Relying on that interpretation, the Missouri Supreme Court held that various claims were not preempted notwithstanding the existence of "specific" federal requirements applicable to the device. Accord *Comeau* v. *Heller*, 1996 WL 670793, at *4 (D. Mass.

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[8] See 116 S. Ct. at 2258 ("[T]he federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect *from potentially contradictory* state requirements.") (emphasis added); *ibid.* (stating that general state-law obligation to use due care is "*no more a threat* to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a workforce") (emphasis added).

Nov. 6, 1996) (*Lohr* "holds that MDA preemption occurs only when a particular state requirement threatens to interfere with a specific federal interest"); *Armstrong* v. *Optical Radiation Corp.*, 50 Cal. App. 4th 580, 57 Cal. Rptr. 2d 763, 770-71 (2d Dist. Ct. App. 1996) (same).

In sharp contrast, other courts have interpreted *Lohr* as turning on the absence of specificity in the relevant state and federal requirements applicable to the device. In *Committee of Dental Amalgam Manufacturers and Distributors* v. *Stratton*, 92 F.3d 807, 812 (9th Cir. 1996), petition for cert. filed, 65 U.S.L.W. 3368 (No. 96-705) (Nov. 4, 1996), the Ninth Circuit held that the MDA preempts state law only if there are a specific federal requirement and a specific counterpart requirement imposed under state law. The Ninth Circuit concluded that California's Proposition 65, which requires all product manufacturers to provide warnings concerning risks of chemicals that cause cancer or reproductive toxicity, is not preempted because it is a "law of general applicability" that "applies to all products and services that pose a health risk to the public." *Id.* at 813; see also *Duvall* v. *Bristol-Myers-Squibb Co.*, 1996 U.S. App. LEXIS 33037, at *21 (4th Cir. Dec. 18, 1996) (stating that the "essence of the holding" in *Lohr* was that MDA "gives rise to preemption when the FDA has imposed specific requirements on a particular device"); *Berish* v. *Richards Medical Co.*, 937 F. Supp. 181 (N.D.N.Y. 1996) (interpreting *Lohr* as turning on the absence of specificity in the federal requirements applicable to the Medtronic pacemaker lead); *Kernats by Kernats* v. *Smith Industries Medical Systems*, 669 N.E.2d 1300 (1st Dist. Ct. App.) (applying two-part test focusing on specificity of federal and state requirements), appeal denied (Ill. Dec. 4, 1996); *Walker* v. *Johnson & Johnson Vision Products*, 217 Mich. App. 705, 552 N.W.2d 679, 687 (Mich. Ct. App. 1996) (rejecting argument that premarket approval process imposes requirements that are sufficiently specific to trigger preemption under *Lohr*); *Askenazi* v. *Hymil Mfg. Co.*, 648 N.Y.S.2d 895, 898 (Kings Cty. Sup. Ct. 1996) (*Lohr* "held that the MDA would preempt a State or local requirement only if specific counterpart regulations or requirements which are applicable to a particular device exist").

If the *Lohr* majority's decision hinged on the notion of "specificity," that concept is itself highly ambiguous and susceptible to

multiple interpretations, as Justice Breyer's opinion appears to acknowledge. See 116 S. Ct. at 2261 (stating that "[i]nsofar as there are any applicable FDA requirements here," they "are not 'specific' *in any relevant sense*") (emphasis added). Under the FDA's regulation, for example, a requirement is "device-specific" *either* (1) if it does not relate to "'products in addition to devices'" (*id.* at 2257 (quoting 21 C.F.R. § 808.1(d)(1)), *or* (2) if it relates to devices themselves as opposed to device *manufacturers* or *places* where devices are manufactured. See 21 C.F.R. § 808.1(d)(1); 43 Fed. Reg. 18663. Within the first category, moreover, it is not at all clear whether a requirement that applies beyond a single device, or beyond a single "class" of devices, qualifies as a requirement that is "'specific' to a 'particular device.'" 116 S. Ct. at 2257 (quoting 21 C.F.R. § 808.1(d)). And finally, neither of the FDA's definitions involves the most obvious meaning of "specificity" in this context: specificity in the *content* or *substance* of a requirement.[9]

Here again, it will be left to the lower courts to sort out which of these definitions of "specificity" — or which combination — must be employed before state requirements are subject to preemption (or federal requirements trigger preemption). The lower courts already are sharply divided over how *Lohr* should be

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[9] To give an example of this last meaning, the duty to *exercise due care* in designing a pacemaker is much less "specific" in nature than is the duty (mentioned in Justice Breyer's opinion) to *use a one-inch wire*. See 116 S. Ct. at 2259 (Breyer, J.). Such "content-specificity," however, is quite different from the "device-specificity" concept employed by the FDA. To give another example, a state-law requirement might command product manufacturers to provide a particular warning with their products, but that requirement would not be "device-specific" under the FDA's regulation if it applied to products other than medical devices (or perhaps even to more than a single device or class of devices). Without explanation, the *Lohr* majority at several points appeared to have this concept of "content-specificity" in mind. See 116 S. Ct. at 2257 (opinion of Stevens, J.) (Congress wanted preemption to occur only where there is a "particular state requirement"); *id.* at 2258 (stating that federal requirements applicable to pacemaker are not preemptive because of their "generality" and contrasting case where federal government imposes a "specific mandate on manufacturers").

applied to medical devices that were not brought to market under Section 510(k) but through other avenues of regulatory review. See Marianne Lavelle, *High Court Medical Devices Ruling Muddles Matters*, NAT'L L.J. A9 (Sept. 30, 1996) ("Courts have split sharply in their reading of a 1996 Supreme Court decision that many had hoped would clear up the issue of when federal regulatory law preempts actions based on state tort and other law."). Thus, state and federal courts have reached conflicting results in their efforts to apply *Lohr* to devices that are investigational (so-called "IDE" devices).[10] Similarly, courts have reached conflicting results in applying *Lohr* to devices that are subject to premarket approval (so-called "PMA" devices).[11]

E. Even outside of cases involving MDA preemption, *Lohr* is likely to create uncertainties over the relationship between implied and express preemption because of inconsistencies between the analysis in the Stevens and Breyer opinions and this Court's analysis in other recent cases involving express preemption.

Before this Court's decision four and a half years ago in *Cipollone*, it was settled law that there are two separate doctrines of preemption — express preemption and implied preemption. Express preemption occurs when Congress includes a preemption provision in a statute. Implied preemption occurs when Congress's intent to preempt state law may be inferred from other features of the statute (such as its comprehensiveness, as in "field" preemption), or by virtue of the Supremacy Clause itself (as where state law conflicts with federal law). "Conflict" preemption, in turn,

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[10] Compare, *e.g.*, *Connelly* v. *Iolab Corp.*, *supra* (MDA does not preempt claims regarding IDE device), with *Berish* v. *Richards Medical Co.*, *supra* (MDA preempts claims relating to IDE device unless state and federal requirements are identical).

[11] Compare, *e.g.*, *Walker* v. *Johnson & Johnson Vision Products*, 217 Mich. App. 705, 552 N.W.2d 679, 687 (Mich. Ct. App. 1996) (MDA does not preempt claims relating to PMA devices), and *Armstrong* v. *Optical Radiation Corp.*, 50 Cal. App. 4th 580, 57 Cal. Rptr. 2d 763 (2d Dist. Ct. App. 1996) (same), with *Green* v. *Dolsky*, 1996 Pa. LEXIS 2317 (Pa. Nov. 22, 1996) (MDA preempts claims of negligent development, failure to warn, and strict liability relating to PMA devices).

includes not only instances of actual conflict between the mandates of state and federal law, but also cases where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. 132, 143 (1963).

Two sentences in *Cipollone* led lower courts to question whether the established framework remained valid. The Court suggested, almost in passing, that "the preemptive scope" of a federal statute governing tobacco advertising was "governed entirely by the express language" of the statute. 505 U.S. at 517. The Court added that, "[w]hen Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a reliable indicium of congressional intent with respect to state authority, there is no need to infer congressional intent to preempt from the substantive provisions of the legislation." *Ibid.* (internal quotation marks and citation omitted).

A majority of the federal courts of appeals understood this Court to be saying that resort to arguments about implied preemption is completely *foreclosed* in cases involving statutes that contain express preemption clauses (at least if such clauses provided a "reliable indicium" of Congress's preemptive intent). In *Freightliner Corp.* v. *Myrick*, 115 S. Ct. 1483 (1995), however, the Court disavowed that interpretation of *Cipollone*. The Court explained that it had not intended to express a "categorical rule precluding the coexistence of express and implied preemption." *Id.* at 1488. Instead, *Cipollone* "[a]t best * * * supports an inference that an express preemption clause forecloses implied preemption." *Ibid.* Apart from clearly rejecting the lower courts' reading of *Cipollone*, the Court in *Myrick* left the relationship between implied and express preemption somewhat unclear.

Without making any reference to these statements in *Cipollone* and *Myrick*, the majority in *Lohr* appears to have suggested that it is appropriate to interpret an express preemption provision by reference to principles of implied preemption. Both the plurality opinion and Justice Breyer's separate concurrence invoke concepts drawn from the law of implied preemption. See pages 10-11, *supra*. By relying on principles of implied preemption in

construing an express preemption clause, the Court's decision threatens to spawn renewed confusion in the lower courts.[12]

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Our submission is simple: the plurality opinion in *Lohr*, and Justice Breyer's separate opinion, have created critical ambiguities in the construction of the MDA and preemption law generally, and those ambiguities already have generated — and no doubt will continue to generate, see note 20, *infra* — substantial confusion in the lower courts. Rather than require lower courts and litigants to speculate as to this Court's rationale in this important area of the law, the Court should seize the opportunity to grant plenary review and revisit its *Lohr* analysis.

II. The *Lohr* Opinions Contain Serious Errors

Although the ambiguities discussed above (and the uncertainties they have created) provide sufficient reason to grant plenary review, this Court also should reconsider *Lohr* because of a number of serious errors in the analysis of the Justices who made up the majority.

A. *Ambiguity In The Statutory Text.* Justice Stevens's and Justice Breyer's opinions both conclude that the language of Section 360k(a) is ambiguous. Section 360k(a) provides:

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[12] The lower courts are already divided over whether *Lohr* alters the holding of *Cipollone*. Compare *Lewis* v. *American Cyanamid*, 682 A.2d 724, 729 (N.J. App. Div. 1996) (*Lohr* "is not inconsistent with *Cipollone*"), with *Askenazi*, 648 N.Y.S.2d at 897 (*Lohr* "narrowly limits the holding of *Cipollone*"). The courts also have reached conflicting results over whether the reasoning of *Lohr* applies to express preemption under other statutes. Compare *Askenazi*, 648 N.Y.S.2d at 897 (applying *Lohr* to preemption under the Flammable Fabrics Act, 15 U.S.C. § 1203), and *Ketchum*, 49 Cal. App. 4th at 1677-78 (applying *Lohr* to preemption under the National Traffic and Motor Vehicle Safety Act, 49 U.S.C. § 30103(b)), with *Lewis*, 682 A.2d at 730-32 (refusing to apply *Lohr* to preemption under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136v), and *Verb* v. *Motorola*, 1996 Ill. App. LEXIS 236, at *19 (1st Dist. Ct. App. Nov. 12, 1996) (refusing to apply *Lohr* to preemption under the Electronic Product Radiation Control Act, 21 U.S.C. § 360kk(a)(1)).

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use *any requirement* — (1) which is different from, or in addition to, *any requirement* applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added). Based on a determination that this language is ambiguous, the majority afforded significant weight to the FDA's "narrow" interpretation of the preemption provision (116 S. Ct. at 2257 n.18). The Court's premise concerning statutory ambiguity, however, was erroneous.

According to Justice Stevens's opinion for a plurality, "if Congress intended to preclude all common-law causes of action, it chose a singularly odd word with which to do it." 116 S. Ct. at 2251. Justice Stevens stated:

> The statute would have achieved an identical result, for instance, if it had precluded any "remedy" under state law relating to medical devices. "Requirement" appears to presume that the State is imposing a specific duty upon the manufacturer * * *.

Ibid. (citation omitted). Justice Stevens further observed that the word "requirements" is used many times in the MDA, and in each instance it "is linked with language suggesting that its *focus* is device-specific enactments of positive law by legislative or administrative bodies." *Id.* at 2252 (emphasis added).

This analysis is seriously flawed. First, contrary to Justice Stevens's suggestion, if the statute had mentioned "remedies" only, it would not necessarily have reached the underlying substantive *standards* relating to the design, labeling, or manufacture of medical devices that are enforced through a variety of state remedies (much less state standards and requirements as to which there is no private "remedy" at all but only the possibility of state-government enforcement). Indeed, Justice Stevens elsewhere appears to have acknowledged this point, by suggesting that the word "remedies" does not include "requirements." See 116 S. Ct. at 2255 ("The presence of a damages *remedy* does not amount to the additional

or different '*requirement*' that is necessary under the statute * * *."). Thus, the statute would have had to refer, at a minimum, to both "remedies" *and* "requirements" in order to reach all of the state law envisioned by the plurality. The critical question, therefore, was whether the addition of the word "remedies" was necessary in order for the statute (which already must mention "requirements") to reach common law duties. And, as a majority of this Court concluded in *Lohr* — and as the Solicitor General expressly conceded on behalf of the expert federal agency — that question was effectively answered in Medtronic's favor in *Cipollone*. 116 S. Ct. at 2259-60 (Breyer, J.); *id.* at 2262-63 (O'Connor, J.); Nos. 95-754, 95-886 U.S. Br. 15-19.

Second, the fact that other uses of the word "requirement" elsewhere in the statute are intended to *include* references to "positive law by legislative or administrative bodies" hardly demonstrates that Congress intended, in those instances, to *exclude* common law requirements. Indeed, such a distinction would make little sense, because in many states common law requirements have been codified by statute.[13]

For entirely different reasons, Justice Breyer found even greater ambiguity in Section 360k(a). 116 S. Ct. at 2260 (describing the preemption provision as "highly ambiguous"). According to Justice Breyer, Section 360k(a) "makes clear that federal requirements may preempt state requirements, but it says *next to*

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[13] Justice Stevens cited subsections (a)(2) and (b) of Section 360k as examples of provisions that use the word "requirement" to "refer only to statutory and regulatory law that exists pursuant to the MDA itself." 116 S. Ct. at 2252. Those provisions, however, refer not just to "requirements" but to "requirement[s] *applicable under this chapter*" and to "requirement[s] *under this chapter*." 21 U.S.C. § 360k(a)(2), 360k(b) (emphasis added). Nor is it surprising that, on the *federal* side of the equation, the "requirements" referred to in the MDA would "focus" on statutory and regulatory law: the MDA itself imposes a number of requirements, and the FDA is empowered to create additional requirements as well. Notably, Justice Stevens made no effort to reconcile his interpretation with the views of the Solicitor General, who conceded that under Section 360k(b) a State could "request an exemption for a common-law 'requirement.'" Nos. 95-754, 95-886 U.S. Br. 18.

nothing about just when, where, or how, they may do so." *Ibid.* (emphasis added). He elaborated:

> The words "any [state] requirement" and "any [federal] requirement," for example, do not tell us *which* requirements are at issue, for *every* state requirement that is not identical to even *one* federal requirement is "different from, or in addition to" that single federal requirement; yet, Congress could not have intended that the existence of one single federal rule, say, about a 2-inch hearing aid wire, would preempt *every* state law hearing aid rule, even a set of rules related only to the packaging or shipping of hearing aids. Thus, Congress must have intended that courts look elsewhere for help as to just which federal requirements pre-empt just which state requirements, as well as just how they might do so.

Ibid. With respect, that analysis overlooks key points. First, it ignores the concession by both parties in *Lohr* as well as by the Solicitor General that the MDA's preemption provision requires subject-matter equivalence. That is, the state and federal requirements must relate to the same subject matter, such as labeling or manufacturing standards; a federal labeling requirement does not preempt a state design requirement. This subject-matter equivalency requirement is discernible from the language and structure of the preemption provision (which is framed in terms of a comparison between state and federal requirements that are "different" or "addition[al]" and which preempts, among other things, state requirements that "relate[ ] to * * * any other matter included in a [federal] requirement" applicable to the device).

Second, Justice Breyer's analysis erroneously treats as *ambiguous* — and therefore subject to narrow construction — language that is in fact *unambiguously broad*. Section 360k(a), which twice states that "*any* requirement" that satisfies certain conditions is preempted, is certainly not narrow. The fact that Congress included few significant limitations in the sweep of the MDA's preemption provision is a reason to hold that the statute is broadly preemptive, not a reason to defer to an agency interpretation that

the Court — and the agency — conceded is "narrow." 116 S. Ct. at 2257 n.18; 42 Fed. Reg. 30383.[14]

Section 360k(a) simply is not ambiguous enough to accommodate the majority's holding. To correct this error, the Court can and should grant plenary review in this case.

B. *Deference To The FDA's Regulation Interpreting The MDA's Preemption Provision.* As explained above (at pages 9-10), the opinions of Justices Stevens and Breyer in *Lohr* both relied to a substantial (but undefined) degree on an FDA regulation that narrowly interprets the MDA's express preemption provision. Even if deference under *Chevron* were appropriate in this special context (but see pages 24-28, *supra*), the *Lohr* majority was wrong to rely on this particular FDA regulation for the conclusion that only "specific" requirements are preempted (or trigger preemption) under the MDA.

Contrary to the majority's assumption, the FDA's *actual practice* in considering exemptions from preemption has been *inconsistent* with the regulation's interpretation of the MDA preemption clause. The majority in *Lohr* was flatly wrong in relying on the mistaken view that "the FDA has never granted, nor, to the best of our knowledge, even been asked to consider granting, an exemption for a state law of general applicability." 116 S. Ct. at 2257. On the contrary, the FDA has repeatedly treated state requirements that are *not* "specific" — because they are not limited to a particular medical device or even to medical devices in general — as eligible for an exemption from the express preemption clause. Perhaps the best example is California's Sherman Food, Drug and Cosmetic Law, which contains numerous provisions that pertain to drugs as well as to medical devices and which the FDA

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[14] Of course, Congress *did* limit the class of state requirements subject to preemption by specifying that they must both (1) be "different from, or in addition to," the federal requirement on the same subject matter, and (2) "relate[ ] to the safety or effectiveness of the device or to any other matter included in a [federal] requirement applicable to the device under th[e MDA]." 21 U.S.C. § 360k(a) (emphasis added). An analysis faithful to congressional intent must focus on *those* limitations, not limitations made up by the agency or a court in a quest to construe narrowly a statute that is unambiguously broad.

has considered for exemption under Section 360k(b). See 44 Fed. Reg. 19440; 21 C.F.R. § 808.55(b)(1). Similarly, the FDA has determined that Section 360k(a) preempts a California provision that makes it unlawful "for any person to advertise any *drug or device*, represented to have any effect in any of the following conditions, disorders, or diseases: * * * (m) diseases or disorders of the ear or auditory apparatus, including hearing loss and deafness." 21 Cal. Health & Safety Code § 26463(m) (1984) (emphasis added). According to the FDA, this provision is preempted "to the extent that it applies to hearing aids." 21 C.F.R. § 808.55(b)(2); 45 Fed. Reg. 67322. There would be no need for the FDA even to have considered the foregoing provisions for exemption if, as the *Lohr* Court's reading of the FDA's regulation suggests, the MDA's preemption provision does not reach requirements that are not "device-specific."

The agency's lawyer in *Lohr* — the Solicitor General — not only declined to ask this Court to defer to the FDA's interpretation, but also *expressly disagreed* with the "specificity" gloss the agency placed on the statutory text.[15] Instead of endorsing the FDA's interpretation, the Solicitor General's brief offered an entirely new distinction that was nowhere articulated in the FDA's regulation or in the notices accompanying it: a distinction between "substantive" requirements imposed by state law and "remedies or

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[15] See Nos. 95-754, 95-886 U.S. Br. 24 n.19 (conceding that FDA's regulations concerning Good Manufacturing Practices, which are general in nature and apply to numerous types of devices, are "requirements" that trigger preemption under Section 360k(a)); *id.* at 18 (casting doubt on the FDA's distinction between state requirements that are "generally applicable" to products other than medical devices and those that are "device-specific" by noting that the language of Section 360k(a) "suggests that * * * a [state] requirement *may be one of general applicability*") (emphasis added); *id.* at 13-14 (casting doubt on FDA's distinction between requirements that apply to devices themselves as opposed to device manufacturers or places where devices are manufactured by noting that "[t]he term 'requirement' in [Section 360k(a)] is most naturally read to refer to the attributes of the device itself *or to substantive duties imposed on persons who manufacture or sell it*, rather than to remedial provisions") (emphasis added).

other means of enforcing rights or duties." Nos. 95-754, 95-886 U.S. Br. 13-14.

The Solicitor General had good reason to disavow the FDA's "specificity" gloss: it makes utterly no sense. Under that gloss, a state statute mandating that all medical products (or even, for example, intraocular lenses and one other class of medical devices) bear a certain warning would not be "device-specific" and therefore would not be preempted, but a statute limited to intraocular lenses and imposing an identical requirement would be preempted. There is simply no reason to attribute to Congress such an absurd design, which would empower States to avoid preemption through skillful drafting of laws. Nor is there any reason to think that Congress cared about the form, as opposed to the content, of state requirements applicable to medical devices.

Precisely because the "specificity" limitation makes no sense, this Court has repeatedly rejected invitations to read similar limitations into other express preemption provisions. In *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374 (1992), for example, this Court interpreted a provision of the Airline Deregulation Act of 1978 ("ADA") that "pre-empts the States from 'enact[ing] or enforc[ing] any law, rule, regulation, standard or other provision * * * relating to rates, routes, or services of any air carrier.'" *Id.* at 383 (quoting 49 U.S.C. App. § 1305(a)(1)). The Court categorically rejected the argument that "only state laws specifically addressed to the airline industry are preempted, whereas the ADA imposes no constraints on laws of general applicability." *Id.* at 386. Such an interpretation, this Court noted, would create "an *utterly irrational loophole*." *Ibid.* (emphasis added); accord *Pilot Life Ins. Co.* v. *Dedeaux*, 481 U.S. 41, 47-48 (1987) (ERISA preemption is not limited to state measures targeting ERISA plans but also includes more general common law tort and contract causes of action); *San Diego Building Trades Council* v. *Garmon*, 359 U.S. 236, 244 & n.3 (1959) ("Nor has it mattered [in cases involving NLRA preemption] whether the States have acted through laws of broad general application rather than laws specifically directed towards the governance of industrial relations.").

The *Lohr* majority made no effort to justify reliance on an agency interpretation that (a) the agency itself does not claim is deserving of deference; (b) the agency's lawyer before this Court

expressly disavowed; (c) the agency has failed to adhere to in practice; *and* (d) has the effect of creating an "utterly irrational loophole" in the statutory scheme designed by Congress.

C. *The Relevance Of Implied-Preemption Principles.* To the extent that the majority in *Lohr* relied on principles of *implied* preemption in construing the MDA's *express* preemption provision (see pages 10-11, *supra*), that reliance was mistaken.

If Congress wishes to accomplish *only* implied preemption, there is no need to include an express preemption provision in a statute. The decision to enact an express preemption provision necessarily reflects a desire to preempt some domain of state law that is *different* from what would otherwise be preempted under ordinary concepts of implied preemption. It therefore makes no sense, as a general matter, to use principles of implied preemption law to illuminate the meaning of an express preemption clause.

Generalities about construction of preemption clauses aside, Section 360k(a) itself provides powerful evidence that it is *not* limited to conflicting requirements. The exemption clause permits the FDA, among other things, to exempt from preemption state requirements that both are "required by compelling local conditions" and may be "compli[ed] with" without "caus[ing] the device to be in violation of any applicable [federal] requirement." 21 U.S.C. § 360k(b)(2). In other words, the MDA permits exemption of state requirements that do *not* conflict with federal requirements. It necessarily follows that some *non-conflicting* state requirements are subject to preemption under Section 360k(a). The language of the preemption clause itself also expressly goes beyond implied-preemption concepts. The preemption of state requirements that are "in addition to" applicable federal requirements on the same subject matter reaches well beyond "conflicting" state requirements. The same can be said of "different" state requirements: state requirements can be different without conflicting with, or frustrating the purpose of, applicable federal requirements. The statutory text is therefore far broader in its reach than are principles of implied preemption.

We respectfully submit that the Court's invocation of implied-preemption provisions as an aid to interpretation of this express preemption clause was not well thought through. Reasoned con-

struction of Section 360k(a) would benefit from plenary consideration of the present case.

III. Plenary Review Should Be Granted To Resolve The Important Threshold Issue Whether *Chevron* Deference Is Owed To An Agency's Interpretation Of An Express Preemption Clause

The *Lohr* majority's heavy reliance on the FDA's regulation conflicts with a prior decision of this Court and is likely to compound the confusion that already exists in the lower courts concerning how much weight, if any, courts should accord to an agency's interpretation of an express preemption clause. The Court should grant plenary review to resolve this important and recurring issue concerning the proper application of *Chevron*.

The majority's reliance on the FDA's regulation is inconsistent with *Louisiana Public Service Commission* v. *FCC*, 476 U.S. 355 (1986), a post-*Chevron* decision. *Louisiana Public Service Commission* involved an FCC rule prescribing how telephone companies must calculate the depreciation of telephone plant and equipment for purposes of calculating costs during ratemaking. The issue was whether the FCC had the authority to establish such rules not only for interstate services but also for intrastate services. In arguing that its regulation was preemptive with respect to intrastate services, the FCC relied on several provisions of the Communications Act, which the agency claimed were preemptive of state-agency jurisdiction. See 476 U.S. at 366-68. Both the FCC and the private respondents argued that this Court should defer to these agency interpretations.[16]

In holding that state jurisdiction was not preempted, this Court gave no deference to the agency's view that the statutory provisions, properly interpreted, afforded preemptive effect to the FCC's regulation. And it did so while acknowledging that the statute contained "vague language" and "areas of uncertainty" (476 U.S. at 379), that the meaning of the statutory text was neither

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[16] See Nos. 84-871, 84-889, 84-1054, 84-1069 U.S. Br. 20-23, 26; Paul E. McGreal, *Some Rice With Your Chevron?: Presumption and Deference in Regulatory Preemption*, 45 CASE WES. L. REV. 823, 886 & nn.315-16 (1995).

"unambiguous" nor "straightforward" (*id.* at 377), and that it was "possible to find some support in the broad language of the [provision] for [the agency's] position" (*ibid.*). See McGreal, *supra*, 45 CASE WES. L. REV. at 886-87 (fact that "*Louisiana Public Service Commission* * * * made no reference to *Chevron* or deference to an agency's statutory interpretation in the face of an ambiguous statute" suggests that the Court was of the view that "*Chevron* deference does not apply to an agency's interpretation of Congress's preemptive intent").

This Court recently took note of, but found it unnecessary to decide, the question whether *Chevron* deference should be accorded to an agency's interpretation of an express preemption provision. See *Smiley* v. *Citibank*, 116 S. Ct. 1730, 1735 (1996) ("We may assume (without deciding) that the [question of whether a statute is preemptive] must always be decided de novo by the courts."). On at least three occasions (including one since *Lohr*), the D.C. Circuit has reserved this issue.[17] See also *Teper* v. *Miller*, 82 F.3d 989, 997-98 (11th Cir. 1996) (stating views of Kravitch, J., only) (identifying issue of "court's obligation to defer" under *Chevron* to agency's interpretation of express preemption clause as "knotty issue of jurisprudence" that is "unsettled"). The courts of appeals that *have* decided the *Chevron* issue, moreover, have reached conflicting results, thus demonstrating the need for this Court to address the issue squarely.[18]

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[17] See *Commonwealth of Massachusetts* v. *United States Department of Transportation*, 93 F.3d 890, 894 (D.C. Cir. 1996) ("[n]either the Supreme Court nor this one has ever definitively decided" whether an agency's interpretation of "an explicit preemption provision in a statute" is "reviewed according to *Chevron*"); *Illinois Commerce Comm'n* v. *ICC*, 879 F.2d 917, 921 (D.C. Cir. 1989) (reserving issue); *City of New York* v. *FCC*, 814 F.2d 720, 726 (D.C. Cir. 1987) (same), aff'd on other grounds, 486 U.S. 57 (1988).

[18] Compare *Gustafson* v. *City of Lake Angelus*, 76 F.3d 778, 786 (6th Cir.) (court must "give great deference" under *Chevron* to the FAA's conclusion that Congress did not "expressly or impliedly * * * preempt regulation of local land or water use in regard to the locations of airports or plane landing sites"), cert. denied, 117 S. Ct. 81 (1996); *Elizabeth Blackwell Health Center for Women* v. *Knoll*, 61 F.3d 170, 181-83 (3d

Indeed, the majority's peculiar handling of the issue in *Lohr* is likely to create even greater confusion in the lower courts on this important and recurring issue of administrative law. Not only did the majority rely heavily on the FDA's interpretation, in apparent conflict with *Louisiana Public Service Commission*, but also it appeared to apply a measure of deference that is less than that required by *Chevron* itself. See pages 9-10, *supra*. The majority, however, did not explain what this new intermediate kind of deference entails, nor did it make any attempt to justify this result in light of the policies and concerns underlying *Chevron*.

There are sound reasons why courts should refuse to apply *Chevron* deference to agency interpretations of express preemption clauses. Express preemption provisions are, by their very nature, intended to be judicially enforced and interpreted in lawsuits between private parties rather than interpreted by administrative agencies. See *Adams Fruit Co.* v. *Barrett*, 494 U.S. 638, 649-50 (1990) (*Chevron* deference is not owed to an agency interpretation

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Cir.) (deferring under *Chevron* to Director of Medicaid Bureau's interpretation of preemptive effect of the Hyde Amendment), cert. denied, 116 S.Ct. 816 (1996); *Brannan* v. *United Student Aid Funds, Inc.*, 94 F.3d 1260, 1263 (9th Cir. 1996) (deferring to Secretary of Education's interpretation of Higher Education Act as preempting state law); and *Teper* v. *Miller*, 82 F.3d 989, 998-99 (11th Cir. 1996) (setting forth views of Kravitch, J., only) (deferring to FEC's interpretation of preemption provision of Federal Election Campaign Act), with *Grunbeck* v. *Dime Savings Bank*, 74 F.3d 331, 341 (1st Cir. 1996) (refusing to give *Chevron* deference to an administrative agency's interpretation of a statutory preemption provision "based exclusively on [the agency's] reading of the bare statutory language"); *Knoll*, 61 F.3d at 185 (Nygaard, J., dissenting) (deference to agency's interpretation of express preemption clause represents "not deference due, but deference run amok"); *Brannan*, 94 F.3d at 1268 (Fletcher, J., dissenting) (*Chevron*'s principles "do not readily apply in the preemption context" because "preemption is a matter of Congressional intent, not the Secretary's"); and *Teper*, 82 F.3d at 1001 (Hill, J. dissenting) (declining to grant deference). See also *Garrelts* v. *Smithkline Beecham Corp.*, 943 F. Supp. 1023, 1040-42, 1044 (N.D. Iowa 1996) (expressly disagreeing with Judge Kravitch's analysis in *Teper* and concluding that "*Chevron* is simply not applicable to the question of agency preemption").

of provisions that were meant to be interpreted by the judiciary rather than the Executive Branch); *Crandon* v. *United States*, 494 U.S. 152, 177 (1990) (Scalia, J., joined by O'Connor & Kennedy, JJ., concurring in the judgment) (*Chevron* deference is not owed to agency interpretations of provisions that are "not administered by any agency but by the courts").[19]

In *City of New York* v. *FCC*, Judge Mikva filed a separate opinion pointing out that this Court "gave *no* deference to the agency's interpretation" in *Louisiana Public Service Commission* and describing as "alarming" the suggestion that *Chevron* deference might be appropriate in this context. 814 F.2d at 729 (Mikva, J., concurring in part and dissenting in part) (emphasis in original). As Judge Mikva explained, concerns about institutional competence and federalism counsel against applying *Chevron* deference when an administrative agency interprets a preemption provision *broadly* in favor of greater preemption. *Id.* at 728-29; *id.* at 729 (agency's "assertion of federal *preemptive* authority is not equivalent to an agency's adoption of a rule to fit its statutory mission") (emphasis in original). It is difficult to see how a different approach could be sustained under *Chevron* when the agency is instead interpreting an express preemption provision *narrowly*. Indeed, the latter scenario raises the specter — realized in this case — that an agency will thwart Congress's will by preserving more state law than Congress intended in order to avoid shouldering new regulatory responsibilities that Congress wished to assign exclusively to the federal regulator. See Cass R. Sunstein, *Law and Administration After Chevron*, 90 COLUM. L. REV. 2071, 2100 (1990) (*Chevron* deference is inappropriate when there is a risk of "abdication of enforcement power"). For all of these reasons, *Chevron* deference is inappropriate in this context.

Had the majority in *Lohr* squarely faced and resolved the threshold *Chevron* issue, it should have concluded that deference was inappropriate (and that the Lohrs' manufacturing and labeling

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[19] See also *Knoll*, 61 F.3d at 196 (Nygaard, J., dissenting) (concerns underlying *Chevron* are not controlling "in the context of preemption"; federal agencies lack power to preempt state law through interpretative rules because "it takes law to displace law").

claims were preempted). In view of the divergent views taken by the lower courts on this issue, the need for guidance from this Court is manifest.

IV. It Would Conserve Judicial Resources To Revisit *Lohr* At This Time

There is no good reason for this Court to await further percolation in the lower courts before resolving the multiple ambiguities in *Lohr*. As explained above (at pages 11-12, 14, 16 & notes 6, 10-12), the lower courts already are deeply divided over the decision's meaning and proper application, thus demonstrating the need for this Court's prompt intervention. Nor is there any reason to believe that the substantial confusion in the lower courts will dissipate rather than deepen if this Court declines to grant review at this time. Since the ambiguities all stem from this Court's opinions, those ambiguities can be clarified or resolved only by this Court. In fact, the Court's 4-1-4 decision — in which Justice Breyer cast the decisive vote against preemption even while (a) seemingly disagreeing with portions of the plurality opinion he joined and (b) agreeing with substantial parts of the opinion supporting preemption — is *inherently* certain to cause confusion until this Court itself clarifies matters, since lower courts must sort out those instances in which the Breyer and O'Connor opinions represent the majority view from those in which the Breyer and Stevens opinions do so. Under these circumstances, this Court should grant plenary review in this case.

Waiting for the lower courts to issue additional decisions interpreting and applying *Lohr* would impose an extraordinary burden on the medical device industry. As this Court is aware, there are many thousands of product-liability actions currently pending in the state and federal courts involving a wide array of medical devices, including intraocular lenses, pacemakers and heart valves, artificial hips and other joints, breast implants, and pedicle screws. In many if not most of these cases, preemption is asserted as a defense and the issue is fully litigated. Not surprisingly, numerous state and federal courts are now actively considering how to apply *Lohr* to various kinds of medical devices.[20] Thus,

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[20] See, *e.g.*, *Martin* v. *Telectronics Pacing Systems, Inc.*, No. 94-4003

the decisional law in this important area of federal law can be expected to continue growing at a rapid pace.

A decision by the Court to decline this opportunity to revisit *Lohr* and wait for some future case would result in a massive waste of judicial resources. It is all but inevitable, we submit, that this Court will need to clarify *Lohr* at some point. In the meantime, litigants and judges will expend substantial resources puzzling over the decision's meaning, only to find that the effort was wasted when those ambiguities are resolved by this Court. By the same token, if the Court were to wait several years before deciding the important *Chevron* issue involved in this case, and then decide that *Chevron* deference is inappropriate in this context, the Court's action likely would cast into doubt a large body of post-*Lohr* case law. For that reason as well, this Court should revisit *Lohr* now rather than later.

This case presents a particularly good opportunity to reconsider the analysis in *Lohr*. As previously explained (at page 3), this case is quite similar to *Lohr*. By using this case as the vehicle to

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(6th Cir.) (pending) (heart defibrillator), on remand, 116 S. Ct. 2576 (1996); *Mitchell* v. *Collagen*, No. 94-3946 (7th Cir.) (pending) (collagen implants), on remand, 116 S. Ct. 2576 (1996); *Oja* v. *Howmedica*, Nos. 95-1085, 95-1104, 95-1123 (10th Cir.) (pending) (artificial knee); *Reeves* v. *AcroMed Corp.*, No. 96-30307 (5th Cir.) (pending) (pedicle screws); *Feldt* v. *Mentor Corp.*, No. CA H 93-2205 (S.D. Tex.) (pending) (penile prosthesis), on remand, 95 F.3d 4 (5th Cir.), on remand, 116 S. Ct. 2575 (1996); *Kemp* v. *Pfizer*, Civ. Action No. 92-40591 (E.D. Mich.) (pending) (heart valve), on remand, 1996 U.S. App. LEXIS 19077 (6th Cir.), on remand, 116 S. Ct. 2575 (1996); *In re Orthopedic Bone Screw Product Liability Litigation*, MDL Docket No. 1014 (E.D. Pa.) (pending) (pedicle screws); *Sanders* v. *Optical Radiation Corp.*, No. CA-94-2039-3 (D.S.C.) (pending) (intraocular lens), on remand, 92 F.3d 1181 (4th Cir. 1996); *Scanga* v. *Johnson & Johnson, Inc.*, D.C. Civ. No. 94-1686 (W.D. Pa.) (pending) (knee prosthesis), on remand, 96 F.3d 1434 (3d Cir. 1996); *Kuper* v. *Steffee*, No. L-123-95 (N.J. Super.) (pending) (pedicle screws); *Dutton* v. *AcroMed Corp.*, Nos. 69332, 69333, 69358 (Ohio 8th Dist. Ct. App.) (pending) (pedicle screws); *Mears* v. *Marshall*, No. CA A85078 (Ore. Ct. App.) (pending) (collagen implants), on remand, 931 P.2d 966 (Ore. 1996); *Fry* v. *Allergan*, No. 95-0221 (R.I. Sup. Ct.) (pending) (intraocular lens).

consider the same issues in a fresh light, the Court can focus directly on those issues, without the distraction of trying to account for factual variations that would complicate the analysis if the Court were to review a less similar case. Moreover, a fresh decision on a factual pattern similar to *Lohr* would give the lower courts clearer guidance than they would likely receive if the Court were to take up a different case.[21] For these reasons, we respectfully submit that this case presents the Court with a unique opportunity to bring much-needed clarity to a troubled but supremely important body of law, an opportunity that the Court should not allow to escape.

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[21] We note, moreover, that one respect in which this case *is* different from *Lohr* — the presence of a claim by plaintiff that Medtronic is not entitled to the preemption defense because it committed a "fraud on the FDA" (see page 2 & note 2, *supra*) — provides an additional reason why plenary review should be granted (and demonstrates why review would be beneficial even if the Court ultimately were to reaffirm its *Lohr* analysis). Prior to *Lohr*, most courts had rejected invitations to create an exception to express preemption under the MDA — and under other statutes, such as FIFRA (7 U.S.C. § 136v), that similarly preempt state requirements that are "different from" or "in addition to" federal requirements — based on a "fraud-on-the-agency" theory. See, *e.g.*, *Talbott* v. *Bard*, 63 F.3d 25, 28-29 (1st Cir. 1995) (MDA), cert. dismissed, 116 S. Ct. 1892 (1996); *Michael* v. *Shiley*, 46 F.3d 1316, 1328-29 (3d Cir.), cert. denied, 116 S. Ct. 67 (1995) (same); *Papas* v. *Upjohn*, 985 F.2d 516, 518-19 (11th Cir.) (FIFRA), cert. denied, 510 U.S. 913 (1993). But see *Evraets* v. *Intermedics Intraocular, Inc.*, 29 Cal. App. 4th 779, 790-91, 34 Cal. Rptr. 2d 852, 858 (2d Dist. 1994) (MDA), review denied (Cal. Feb. 16, 1995). In the aftermath of *Lohr*, courts must determine whether the "fraud-on-the-agency" theory gains any support from this Court's holding that the MDA does not preempt state requirements that are "identical" to federal requirements. The post-*Lohr* decisions already have reached conflicting results on this score. Compare *Lewis* v. *American Cyanamid*, 682 A.2d 724, 732 (N.J. App. Div. 1996) (rejecting "fraud-on-the-EPA" theory under FIFRA) (citing *Michael*), with *Connelly* v. *Iolab Corp.*, 927 S.W.2d 848, 855 (Mo. 1996) (holding "fraud-on-the-FDA" theory not preempted under MDA), and *Green* v. *Dolsky*, 1996 Pa. LEXIS 2317, at *16-17 (Pa. Nov. 22, 1996) (same).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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In the Supreme Court of the United States

OCTOBER TERM, 1996

CATHERINE W. GRIFFIN, PETITIONER

v.

MEDTRONIC, INC., RESPONDENT

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

SUPPLEMENTAL BRIEF FOR THE RESPONDENT

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SUPPLEMENTAL BRIEF FOR THE RESPONDENT

Pursuant to Rule 15.8 of the Rules of this Court, respondent respectfully draws to this Court's attention several significant developments that have occurred since the filing of our brief on December 30, 1996. These developments demonstrate not only that certiorari should be granted, as both petitioners and we have urged, but also that this Court's review should be plenary rather than summary. Even if the Court is disposed to act summarily, this case should be held pending resolution of the petition for a writ of certiorari in *Iolab Corp.* v. *Hunter*, No. 96-1126 (filed Jan. 15, 1997), which raises closely related issues concerning the scope of express preemption under the Medical Device Amendments ("MDA") to the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a).

1. In *Martin* v. *Telectronic Pacing Systems, Inc.*, 1997 U.S. App. LEXIS 1627 (Jan. 31, 1997), the Sixth Circuit on remand from this Court[1] recently held that the MDA expressly preempts a variety of damages claims brought against the manufacturer of an investigational device, including claims under Ohio law for defective manufacture, defective design, failure to warn, express warranty, and loss of consortium. The Sixth Circuit candidly acknowledged that its holding is in conflict with the post-*Lohr* decision of Missouri's highest court in *Connelly* v. *Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996), which held that "causes of action for negligence, strict liability, failure to warn, lack of informed consent, and fraud were *not* preempted in a case involving an * * * investigational device." *Martin*, 1997 U.S. App. LEXIS 1627, at *23 n.6 (emphasis added). The Sixth Circuit's decision thus significantly worsens the division in the lower courts (see Resp. Br. 14 n.10) concerning how *Lohr* should be applied to investigational devices.

The Sixth Circuit's decision also confirms our prediction (see Resp. Br. 28-29) that the lower courts would continue to have great difficulty understanding and applying this Court's fractured decision in *Lohr*. Even before *Martin* the lower courts were

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[1] 116 S. Ct. 2576 (1996) (granting petition, vacating decision below, and remanding for reconsideration in light of *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240 (1996)).

deeply divided over whether the holding in *Lohr* hinged on the absence of a *conflict* or rather on the absence of federal and state requirements of sufficient *specificity*. See Resp. Br. 10-12. The Sixth's Circuit's decision is likely to compound this confusion because it treats the "specificity" and "conflict" rationales as *alternative means* by which a federal requirement may qualify to trigger preemption (or a state requirement may qualify to be subject to preemption).

The Sixth Circuit reasoned that, "[u]nlike the general federal requirements discussed in [*Lohr*], the [federal] regulations governing investigational devices are essentially device specific" and therefore trigger preemption under the MDA. *Martin*, 1997 U.S. App. LEXIS 1627, at *19; see also *id.* at *25, *30. On the other hand, when it came to evaluating the alleged *state* common law and statutory requirements underlying plaintiff's various product-liability and other claims, the Sixth Circuit relied on the "conflict" rationale in holding that those state requirements were subject to preemption:

> [I]t is questionable whether the [Ohio product liability statute] is "with respect to" a medical device and not simply of general applicability. In [*Lohr*], the state common law requirements regarding manufacturing were not specifically developed "with respect to" medical devices and were not the kinds of requirements that would impede the implementation and enforcement of specific federal requirements. [*Lohr*] at 2258. The state requirement regarding negligent manufacturing was simply "the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products." *Id.* at 2258. The same cannot be argued with respect to the generally applicable statute in question [here] because it is the kind of requirement that would *impede the implementation and enforcement of specific federal requirements*. *Id.*

Id. at *25-*26 (emphasis added).[2] Compare, *e.g.*, *Dutton* v. *Acro-*

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[2] See also 1997 U.S. App. LEXIS 1627, at *28-*29 (design defect claim is preempted even though it imposes requirements that "appear[ ] not specifically applicable solely to medical devices," because to permit claim to proceed "would impede the implementation and enforcement of

med Corp., 1997 Ohio App. LEXIS 97, at *14 (8th Dist. Ct. App. Jan. 16, 1997) (in rejecting argument that state failure-to-warn claim is preempted by MDA, stating that "these state requirements escape preemption because they apply to all products generally, not only to medical devices").

What is more, the Sixth Circuit's discussion of the "specificity" test as applied to the federal regulations governing investigational devices strongly confirms the essential indeterminacy of that concept. As we explained (Resp. Br. 12-13), the concept of "device-specificity" is susceptible to multiple interpretations. It could mean that the requirement relates only to medical devices and not to other kinds of products. See Resp. Br. 13. It could mean that the requirement is limited to a single device (such as one model of pacemaker made by a particular manufacturer) or to one type of device (such as all pacemakers). *Ibid.* It could mean that the requirement is imposed on the device itself (as opposed to the manufacturer or the manufacturing site). *Ibid.* Or it could mean that the requirement is narrow or specific in its content or command. *Ibid.* In holding that the federal requirements relating to investigational devices are "device-specific" and thus trigger preemption, the Sixth Circuit added even more candidates to this list of possible interpretations.

For example, the court explained that the federal regulations at issue "specifically apply to investigational devices," thereby suggesting that requirements that target a *regulatory class* of devices qualify as "device-specific." *Martin*, 1997 U.S. App. LEXIS 1627, at *25; see also *id.* at *30 ("Unlike in *Medtronic*, the labeling requirements here are specific in that they apply only to investigational devices; they are not, therefore, generic requirements."). The Sixth Circuit also reasoned that the federal requirements concerning design and manufacturing had become "specific" because the FDA had conducted an extensive review of the specific device in question and had approved it for an investigational exemption. *Id.* at *25, *28. The Sixth Circuit thereby

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specific federal requirements"); *id.* at *31 (failure-to-warn claim is preempted because it would impose requirements that would "impede" federal interests).

suggested that federal requirements that are applicable to many kinds of devices might become "device-specific" if applied to a particular device through a process of extensive regulatory review. But see *Dutton*, 1997 Ohio App LEXIS 97, at *12-*13 (rejecting argument that FDA's specific action with respect to labeling of a particular Section 510(k) device triggers preemption).

In sum, the Sixth Circuit's decision illustrates the serious ambiguities in *Lohr* and will no doubt contribute to the growing doctrinal confusion and uncertainty in this important area of the law.

2. On January 15, 1997, a petition for a writ of certiorari was filed seeking review of the Missouri Supreme Court's decision in *Connelly* v. *Iolab Corp.*, *supra*. *Iolab Corp.* v. *Hunter*, No. 96-1126. We continue to believe that the present case, *Griffin* v. *Medtronic, Inc.*, is the ideal vehicle to reconsider *Lohr* (see Resp. Br. 29-30). Nevertheless, if review is granted in *Iolab* to resolve the clear conflict between the Missouri Supreme Court and the Sixth Circuit, then this Court will have occasion to consider some of the issues that were left undecided in *Lohr* and to clarify, and perhaps to modify, some of the analysis in *Lohr*. For example, *Iolab* (if granted) would give the Court an opportunity to address the question — squarely raised in the present case as well — whether it is appropriate to apply *Chevron* deference to an agency interpretation of an express preemption clause. It would also give the Court an occasion to reconsider the many aspects of *Lohr* that are ambiguous or problematic.

Accordingly, we respectfully request that, if plenary review is not granted in this case, the Court hold this case pending its disposition of the petition in *Iolab Corp.* v. *Hunter*.

CONCLUSION

The petition for a writ of certiorari should be granted, or at minimum, this case should be held pending the disposition of the certiorari petition in *Iolab Corp.* v. *Hunter*, No. 96-1126.

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